REMARKS

The Examiner rejected claims 1 and 5 under 35 U.S.C. §103(a) as allegedly being unpatentable over Lai et al. (US 6306842) in view of Ares et al. (US 5399584), or if necessary further in view of Anderson et al. (US 6248341).

Applicants respectfully traverse the §103 rejections with the following arguments.

35 U.S.C. §103

The Examiner rejected claims 1 and 5 under 35 U.S.C. §103(a) as allegedly being unpatentable over Lai et al. (US 6306842) in view of Ares et al. (US 5399584) and further in view of Anderson et al. (US 6248341).

A first reason why claim 1 is not unpatentable over Lai in view of Ares and further in view of Anderson is that Lai in view of Ares and further in view of Anderson does not teach or suggest "low dose aspirin in the amount of 70-85 mg". The Examiner has not cited any reference that discloses an aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders. In fact, the Examiner specifically admits that Lai does not disclose an aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders. In addition, the Examiner's rejection of claim 1 does not even allege that any of the other cited references (i.e., Ares and Anderson) teach or suggest the aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders, as required by claim 1. Therefore, since the Examiner's rejection has not cited any reference that discloses the aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders, the rejection of claim 1 is per se improper. Accordingly, Applicants respectfully contend that the Examiner has not established a *prima facie* case of obviousness in relation to claim 1.

In addition, the Examiner's argument for rejecting claim 1 is totally silent as to whether the prior art teaches an aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders. Applicants maintain that the Examiner's argument for rejecting of claim 1 has not even addressed the issue of whether the prior art discloses an aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders. Accordingly, the Examiner has not

established a *prima facie* case of obviousness in relation to claim 1.

Moreover, the Examiner has not presented a persuasive reason for modifying Lai to incorporate the aspirin dose of 70-85 mg in Lai's composition, as explained next.

The Examiner presents the following argument as to why it would allegedly be obvious to modify Lai with respect to the aspirin dose of 70-85 mg: "To incorporate such teaching into the teaching of Lai, would have been obvious in view of Ares who teaches the use of flavonoids or flavones for treating damage to the mucosal lining of gastrointestinal tract caused by NSAID. One having ordinary skill in the art would have motivated to modify the teaching of Lai such that gastrointestinal side effects associated with NSAID such as aspirin (column 1, lines 19-22 of Lai' 842; column 1, lines 14-26 of Ares'584) would be greatly reduced."

In response, Applicants contend that the preceding argument by the Examiner relates to modifying Lai by the alleged teaching of Ares to incorporate the use of flavonoids or flavones, but is not an argument for modifying Lai to incorporate the aspirin dose of 70-85 mg. Indeed, the preceding argument by the Examiner presumes (incorrectly) that the aspirin dose of 70-85 mg would cause damage to the mucosal lining of gastrointestinal tract, but does not provide any reason why one would use an aspirin dosage of 70-85 mg in the composition of Lai. Therefore, the preceding argument by the Examiner is not an argument for modifying Lai by the alleged teaching of Ares to incorporate the aspirin dose of 70-85 mg.

The Examiner presents the following alternative arguments as to why it would allegedly be obvious to modify Lai with respect to the use of aspirin in the composition of Ares: "Alternatively, the above references in combination make clear that COX2 inhibitors, aspirin and flavonoids have been individually used for the treatment of inflammatory disorders. It is obvious

to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven,* 205 USPQ 1069 (CCPA 1980)."

In response, Applicants note that the preceding alternative argument by the Examiner is silent as to incorporating the aspirin dosage of 70-85 mg in the composition of Lai. Therefore, the preceding argument by the Examiner is not an argument for modifying Lai to incorporate the aspirin dose of 70-85 mg. In addition, the Examiner's citation of *In re Kerkhoven* for combining aspirin with a COX-2 inhibitor for treating inflammatory disorders is inapplicable to claim 1, since Examiner has not cited any prior art teaching that the aspirin dose of 70-85 mg is known to be useful for treating inflammatory disorders.

In summary, Applicants respectfully contend that the Examiner has not cited any reference that teaches or suggests the aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders, and the Examiner's basis for rejecting of claim 1 has not even addressed the issue of whether the prior art discloses an aspirin dose of 70-85 mg in a composition used to treat inflammatory disorders. In addition, the Examiner has not provided a persuasive reason why it would be obvious to modify Lai to incorporate the aspirin dose of 70-85 mg.

A second reason why claim 1 is not unpatentable over Lai in view of Ares and further in view of Anderson is that Lai in view of Ares and further in view of Anderson does not teach or suggest "antioxidant flavonoids, flavonoids or isoflavones". The Examiner argues that "Ares et al teaches the use of flavonoids for treating damage to the mucosal lining of the gastrointestinal tract (e.g.,

gastrointestinal ulcer) caused by NSAID (abstract, column 3, lines 1630 and lines 46-65)."

In response, Applicants contend that the preceding argument by the Examiner is not persuasive, because the Examiner has not cited any prior art that teaches or suggests that a low aspirin dose of 70-85 mg is a high enough dosage of aspirin to cause damage to the mucosal lining of the gastrointestinal tract. Obviously, there is a dosage of aspirin below which there will be no resulting damage to the mucosal lining of the gastrointestinal tract. Applicants are not aware of any prior art that teaches or suggests that a low aspirin dose of 70-85 mg is a high enough dosage of aspirin to cause damage to the mucosal lining of the gastrointestinal tract. The Examiner has in the burden to present evidence that a low aspirin dose of 70-85 mg would cause damage to the mucosal lining of the gastrointestinal tract, and the Examiner has not provided any such evidence. Of course, if low aspirin dose of 70-85 mg is not a high enough dosage of aspirin to cause damage to the mucosal lining of the gastrointestinal tract, then the Examiner's argument for adding flavonoids to the composition of Lai breaks down and is accordingly not persuasive. If the Examiner is aware of any prior art disclosing that a low aspirin dose of 70-85 mg would cause damage to the mucosal lining of the gastrointestinal tract, then Applicants respectfully request that the Examiner cite such prior art for consideration by Applicants. At present, however, in the absence of such evidence, Applicants respectfully contend that the Examiner has not established a *prima facie* case of obviousness in relation to claim 1.

The Examiner's alternative argument ("Alternatively, the above references in combination make clear that COX2 inhibitors, aspirin and flavonoids have been individually used for the treatment of inflammatory disorders. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from

their having been individually taught in prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven,* 205 USPQ 1069 (CCPA 1980)") is likewise not persuasive with respect to modifying Lai with the alleged teaching of Ares for treating inflammatory disorders, because the Examiner has not presented any evidence showing that a low aspirin dose of 70-85 mg would cause damage to the mucosal lining of the gastrointestinal tract or any other inflammatory disorder.

As to Anderson, the Examiner argues: "Anderson et al teaches the use of flavonoids such as epigallocatechin-gallate, epicatechin gallate for **treating inflammatory disease** (column 2, lines 51-53)" (emphasis added).

In response, Applicants contend that the preceding argument by the Examiner is not persuasive because it is incorrect. In particular, Anderson does not teach in col. 2, lines 51-53 using flavonoids **to treat inflammatory disease** as alleged by the Examiner, Rather, Anderson teaches in col. 2, lines 51-53 that "EGCG and/or ECG can be used **to prevent angiogenesis** caused by chronic inflammatory conditions such as rheumatoid arthritis ..." (emphasis added). Applicants contend that using EGCG and/or ECG **to prevent angiogenesis** caused by chronic inflammatory conditions is not equivalent to using EGCG and/or ECG **to treat chronic inflammatory conditions**. Since the Examiner's argument is based on the **false assumption** that Anderson allegedly teaches "the use of flavonoids ... for treating inflammatory disease", Applicants respectfully contend that the Examiner's argument is confusing, cannot be reasonably understood, and is thus not persuasive.

In addition with respect to modifying Lai by the alleged teaching of Anderson, the

Examiner's citation of *In re Kerkhoven* for combining flavonoids with a COX-2 inhibitor for treating inflammatory disorders is inapplicable to claim 1, since the Examiner's citation of Anderson for allegedly teaching that flavonoids are used to treat inflammatory disorders in incorrect as explained *supra*.

Based on the preceding arguments, Applicants respectfully maintain that claim 1 is not unpatentable over Lai in view of Ares and further in view of Anderson, and that claim 1 is in condition for allowance.

Since claim 5 depends from claim 1, Applicants contends that claim 5 is likewise in condition for allowance.

In addition, Applicants respectfully contend that Lai in view of Ares and further in view of Anderson does not teach or suggest "wherein the low dose aspirin is in an enteric coated formulation". Applicants contend that the Examiner has not presented any argument to show that Lai in view of Ares and further in view of Anderson teaches or suggests the preceding feature of claim 5. The Examiner's rejection of claim 5 has totally ignored the preceding feature of claim 5 and is therefore improper. Accordingly, Applicants respectfully contend that the Examiner has not established a *prima facie* case of obviousness in relation to claim 5.

Applicants respectfully request that the Examiner either present an argument to support the rejection of claim 5 or else indicate that claim 5 is allowable.

CONCLUSION

Based on the preceding arguments, Applicants respectfully believe that all pending claims and the entire application meet the acceptance criteria for allowance and therefore request favorable action. If the Examiner believes that anything further would be helpful to place the application in better condition for allowance, Applicants invites the Examiner to contact Applicants' representative at the telephone number listed below. The Director is hereby authorized to charge and/or credit Deposit Account No. 19-0513.

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